Patient Information Leaflet

Information for the Patient about

CIPLAFAM 125 / 250 TABLETS

Read all of this leaflet carefully before you start taking CIPLAFAM.

- **Keep this leaflet; you may need to read it again.**
- **If you have further questions please ask your doctor or your pharmacist.**
- **CIPLAFLAM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

CIPLAFAM 125 (Tablet)

CIPLAFAM 250 (Tablet)

WHAT CIPLAFAM CONTAINS:

The active substance is famciclovir. **CIPLAFAM 125** and **250** contains 125 and 250 mg of famciclovir, respectively.

WHAT CIPLAFAM IS USED FOR:

CIPLAFAM belongs to a class of medicines called antiviral agents. These medicines are used to treat infections which are caused by viruses.

CIPLAFAM is indicated for the following:

- For the treatment of herpes zoster (shingles) infection.
- For the treatment of the first episode of herpes genitalis, which is a viral infection which is normally spread by sexual contact. It causes blisters and burning around your genitals. **CIPLAFAM** must be taken within 72 hours of appearance of symptoms and within 6 hours of appearance of symptoms in recurrent genital herpes.
- For the suppression of recurrent genital herpes in patients with a normal immune system.

BEFORE YOU USE CIPLAFAM:

Do NOT take CIPLAFAM if you:

- Have a known hypersensitivity (allergy) to famciclovir, penciclovir or any of the ingredients of this medicine.
- Are pregnant or breast feeding (see **"Pregnancy and breast feeding"**).

Take special care with CIPLAFAM:

The presence of other medical conditions may affect the use of **CIPLAFAM**. Tell your doctor or pharmacist if you have any of the following conditions as you may require a lower dose or special monitoring:

- Impaired kidney function.
- If you are using probenecid or other medicines that may influence the function of your kidneys. Please discuss this with your treating doctor or pharmacist.

Genital herpes is a sexually transmitted disease. The risk of transmission is increased during acute episodes. You should avoid intercourse when symptoms (blisters) are present even if you have started taking **CIPLAFAM**.

Although fewer viruses are shed while you are receiving treatment with antiviral medicines, there is still a theoretical possibility that you may pass the infection onto somebody else. You should therefore take appropriate steps for protected intercourse (i.e. use a condom) even while you are using **CIPLAFLAM**.

Use in pregnancy and breast feeding:

The safety of **CIPLAFAM** in pregnancy and breast feeding has not been established.

If you are pregnant or breast feeding your baby while taking CIPLAFLAM, please consult your doctor, pharmacist or other healthcare professional for advice.

Use in children:

There are currently insufficient data on the safety and efficacy of **CIPLAFAM** in children, and therefore its use in children is not recommended.

Taking other medicines with CIPLAFAM

See **"BEFORE YOU TAKE CIPLAFAM"**.

If you are taking other medicines on a regular basis, including complementary and traditional medicines, use of CIPLAFLAM with these other medicines may cause undesirable interactions. Please consult your doctor or pharmacist.

HOW TO TAKE CIPLAFAM:

Always take CIPLAFAM exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults:

Herpes zoster (shingles) infections:

250 mg three times daily for seven days. Treatment should be started as soon as possible, but at least within 72 hours after the blisters (skin rash) first appeared.

First episode genital herpes infections:

Start within 72 hours of appearance of symptoms (blisters) and take 250 mg three times daily for five days.

Recurrent genital herpes infections:

Start within 6 hours of appearance of symptoms and take 125 mg twice a day for five days.

Suppression of recurrent genital herpes infections in patients with normal immune systems:

Take 125 to 250 mg twice daily.

The length of treatment depends upon the severity of the disease. Your doctor should re-evaluate you after 12 months in order to observe possible changes in the natural history of the disease.

Dosage in elderly patients:

Dosage modification is not required unless kidney function is impaired.

Dosage in children:

There are currently insufficient data on the safety and efficacy of **CIPLAFAM** in children, and therefore its use in children is not recommended.

Dosage in patients with impaired kidney function:

Depending on how severely the function of your kidneys is affected, your doctor may reduce your dosage of **CIPLAFAM**. You will have to undergo blood tests to determine your kidney function and based on these results your doctor will decide the most appropriate dosage for you.

Dosage in patients with impaired liver function:

There are no specific recommendations for dosage adjustments in patients with liver disease.

Maximum tolerated daily dose and duration:

Herpes zoster (shingles) patients receiving 750 mg three times daily for seven days tolerated **CIPLAFAM** therapy well. Genital herpes patients receiving up to 750 mg three times daily for 5 days and up to 500 mg three times daily for 10 days also tolerated **CIPLAFAM** well. Good tolerance was also seen in two 12 months studies, in which genital herpes patients received doses of up to 250 mg three times daily.

If you take more CIPLAFAM than you should:

No acute overdosage with **CIPLAFAM** has been reported. Symptomatic and supportive therapy should be given as appropriate. **In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.**

If you forget to take CIPLAFAM:

Take **CIPLAFAM** as prescribed. If you miss a dose of this medicine, take it as soon as possible. However, if you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose.

POSSIBLE SIDE-EFFECTS:

What undesirable effects may **CIPLAFAM** have

CIPLAFAM can have side-effects.

The following side-effects may occur with the use of **CIPLAFAM**:

Side-effects involving the brain and nervous system:

Frequent: Headache, confusion.

Less frequent: Dizziness, excessive sleepiness.

Side-effects involving the gut (stomach and intestines):

Less frequent: Nausea, diarrhoea and vomiting.

Side-effects involving the liver and gallbladder:

Less frequent: Jaundice (yellow discolouration of the skin and whites of the eyes).

Side-effects involving the skin and subcutaneous tissues:

Less frequent: Rash, itching.

Not all side-effects reported for CIPLAFAM are included in this leaflet. Should your general health worsen while taking CIPLAFAM, please consult your doctor, pharmacist or other healthcare professional for advice.

STORAGE AND DISPOSING OF CIPLAFAM:

Store at or below 25 ºC, in a dry place. **STORE THIS MEDICINE OUT OF REACH AND SIGHT OF CHILDREN**.

Keep the aluminium foil strips in the outer carton until required for use.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF CIPLAFAM:

CIPLAFAM 125: Supplied in white, opaque PVC/PVDC and aluminium foil blister strips packed as 10 tablets.

CIPLAFAM 250: Supplied in white, opaque PVC/PVDC and aluminium foil blister strips packed as 15, 21, or 56 tablets.

IDENTIFICATION OF CIPLAFAM:

CIPLAFAM 125: White to off-white coloured, circular, biconvex, film-coated tablets plain on both sides.

CIPLAFAM 250: White to off-white coloured, circular, biconvex, film-coated tablets plain on both sides.

REGISTRATION NUMBERS:

To be allocated.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD.

Rosen Heights

Pasita Street

Rosen Park

Bellville

7530

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